



CONTRACEPTIVE TECHNOLOGY

U P D A T E®

A Monthly Newsletter for Health Professionals

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Mifepristone approval delayed, supporters look to action by FDA

Research and training continue while federal agency weighs facts

While the federal Food and Drug Administration (FDA) continues to analyze information needed for the U.S. marketing approval of the abortion drug mifepristone, supporters are using the time to continue provider training, education, and research of the medical abortion option.

In its Feb. 18 request for information, the FDA again issued an approvable letter on the mifepristone/misoprostol drug regimen, which echoed its original action of Sept. 18, 1996.¹ An approvable letter is an action frequently used by the FDA to indicate that safety and efficacy data have passed agency review but additional information must be submitted before final approval for marketing is granted. (*Contraceptive Technology Update* reported on the FDA's original action in November 1996, p. 141.) New York City-based Danco Laboratories LLC is licensed by the Population Council to make and distribute the drug.

The FDA approval process is moving forward, confirms **Sandra Waldman**, director of public information for the Population Council,

EXECUTIVE SUMMARY

The Food and Drug Administration has again delayed action on marketing approval of the abortion drug mifepristone; however, supporters are using the time to continue provider training, education, and research of the medical abortion option.

- While the FDA says it needs more information before reaching a decision on whether the drug will become available in the United States, it issued an approvable letter on the mifepristone/misoprostol drug regimen, which echoed its original action of Sept. 18, 1996.
- The National Abortion Federation conducted 12 provider training sessions in the first quarter of this year, with presentations scheduled at several national professional provider organizations. It also is developing educational materials for patients and providers.

a nonprofit research center based in New York City that holds the U.S. patent rights to mifepristone. “We are continuing to meet with the FDA and will satisfy all their requests for information,” she says.

The National Abortion Federation (NAF) in Washington, DC, which represents the nation’s largest group of abortion providers, has held 12

regional provider training sessions this year, with more scheduled around the country, reports **Vicki Saporta**, NAF executive director. Average attendance has been 75 at each training session.

In addition, NAF offered a medical abortion track at its

April annual meeting and will make presentations at the annual meetings of the Washington, DC-based American College of Obstetricians and Gynecologists and the Association of Reproductive Health Professionals, both in Washington, DC, the American Medical Women’s Association in Alexandria, VA, the Planned Parenthood Federation of America in New York City, and the Society of Teachers of Family Medicine in Leawood, KS.

“The trainings have received very positive evaluations in the regions where they have been conducted,” notes Saporta. “Providers are very enthusiastic about offering this new technology to patients.”

Look for a supplement on mifepristone to be published in this month’s issue of the *American Journal of Obstetrics & Gynecology*, says Saporta. NAF is putting the finishing touches on its CD-ROM presentation and self-study guide, and it plans to produce videotapes on the subject.

“All of our training is accredited, and the training materials will be the accredited for continuing medical education,” she says. “We

have the finest physicians and clinicians in the country working with us on our materials and our trainings.”

The years of waiting for mifepristone have not been idle or wasted, asserts **Carolyn Westhoff**, MD, MSc, medical director of family planning at Columbia Presbyterian Medical Center and associate professor of clinical OB/GYN and public health at Columbia University in New York City.

“There may be a small silver lining in the [approval] delay in the U.S. because we have had the chance to study innovative protocols,” Westhoff reflects. “The protocols now in use in U.S. clinical studies are more effective, more flexible, and simpler to implement for patients and providers.”

In addition, the time spent waiting on FDA action has allowed the creation of an experienced group of clinician-investigators and counselors, which makes training on this topic much better than it would have been a decade ago, Westhoff says.

The New York-based advocacy group Abortion Rights Mobilization copied the drug in 1994 and has been producing and distributing doses free of charge to more than 5,000 women seeking early abortions at 15 clinics around the country.² The group also is supplying the drug to University of Rochester (NY) School of Medicine scientists, who are looking at use of the drug in shrinking fibroid tumors.² (See **information on mifepristone research in the December 1997 CTU, p. 149.**)

Offer options to women

Providers who are considering offering the mifepristone/misoprostol regimen pending FDA approval should keep several key elements in mind. First, the method is not the important issue, states **Mitchell Creinin**, MD, director of family planning and family planning research and associate professor in the department of obstetrics, gynecology, and reproductive sciences in the University of Pittsburgh School of Medicine.

“There may be a small silver lining in the [approval] delay in the U.S. because we have had the chance to study innovative protocols.”

COMING IN FUTURE MONTHS

- Microbicide research continues
- Teens remain inconsistent contraceptive users
- Latest research on hormone therapy
- Answering your questions about oral contraceptives
- Diagnosis and treatment of STDs in men

Creinin has conducted research on various medical abortion regimens, and he presented on the topic “Mifepristone and Methotrexate in Early Abortion” at the recent *Contraceptive Technology* conferences.

Any woman seeking an abortion must be certain of her decision and be fully counseled about all of her pregnancy options, including early surgical, early medical, delivery, and adoption, says Creinin. “Medical abortion is just that — an abortion,” he explains. “Only once a woman is certain that she wants to not continue the pregnancy should she then decide between medical and surgical options.”

Providers must not fall into a salesperson role when it comes to discussing medical and surgical abortion options, he stresses. “Medical is not always better than surgical, or vice versa. It is the clinician’s responsibility to make sure the patient is fully informed, with truthful information, so that she can decide which option is better for her, given her personal and individual circumstances.”

Women might choose medical abortion because they fear a surgical procedure, an issue that should be addressed during the counseling session, says Creinin. NAF offers a fact sheet, *First Trimester Abortion Options*, which covers the advantages and disadvantages of both medical and surgical abortion. **(For ordering information, see resource box, below right.)** Women must understand the process of medical abortion and the time needed to complete the procedure.

Help women make informed choice

What can women expect from a mifepristone abortion? According to a mifepristone fact sheet prepared by NAF:

- It will take three visits to complete the procedure.
- The average number of days a woman bleeds after taking mifepristone is eight or nine, compared with five for a surgical abortion.

- Some women may see pregnancy tissue.³

“Women who want a medical abortion are really no different, at this point in time, than women who want an early surgical abortion,” Creinin notes. “Women who realize very early that they are pregnant and want to have an abortion are grateful to have a caring clinician who will take care of them as soon as possible, not make them wait until they are further in pregnancy [and have morning sickness], and who

will be honest about the pros and cons of the options.”

Women who choose to have a medical abortion are happiest after the procedure when they have been told upfront the reality of what the experience could be like, concludes Creinin. Common side effects such as cramps similar to those with a heavy period, headache, nausea, vomiting, diarrhea, and heavy bleeding should be discussed.⁴

“It is always easier for the woman if it is not as bad as she anticipated, compared to being worse than she expected,” he notes.

Hotline offers answers

NAF operates a toll-free hotline, (800) 772-9100, to answer women’s questions about mifepristone. It will add more capacity to the hotline pending FDA action, says Saporta. The organization also is developing a Web site to provide further information on the subject.

“We are basically the organization to contact if you are looking for medical abortion materials or training,” she notes. “We also are going to be referring women through our toll-free hotline to qualified service providers in their area.”

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4. National Abortion Federation. “What is Medical Abortion?” Washington, DC, Web: www.prochoice.org/facts/medad.htm. ■

RESOURCE

To order a copy of the fact sheet *First Trimester Abortion Options* (single copies are free) or for more information on abortion services in the United States, contact:

- **National Abortion Federation**, 1755 Massachusetts Ave. N.W., Suite 600, Washington, DC 20036. Telephone: (202) 667-5881. Fax: (202) 667-5890. Web: www.prochoice.org. NAF also operates a toll-free hotline, Monday-Friday, 9 a.m.-7 p.m. EST: (800) 772-9100.

Expand male services: Add no-scalpel vasectomy

Looking for a way to get more men involved in family planning? One Colorado health department has accomplished that goal by offering low-cost no-scalpel vasectomies (NSVs). Since November 1999, more than 10 such male sterilization procedures have been performed at the Jefferson County Department of Health and Environment in Golden, CO. The county health department is the first in its state to offer the service.¹

The department had long considered expanding its services for men past the traditional sports and employment physicals and clinics for sexually transmitted diseases and HIV/AIDS, says **Mark Johnson**, MD, MPH, executive director of the county health department. The impetus for the NSV program came from the state health department, which offered to pay for the provider training and furnish supplemental funding to offset patients' costs for the procedure, he explains.

"We took a look at this, decided it was really an opportunity to expand the treatment of modalities that we do have for males, and got involved," he says.

Training for the Colorado NSV program is part of a two-year project coordinated by AVSC International of New York City, a nonprofit organization dedicated to making reproductive health care accessible to women and men around the

world. AVSC pioneered the introduction of NSV in the United States in 1988 following its 1985 visit to China to learn the vasectomy technique developed by Li Shunqiang, MD.² The NSV technique is less invasive, less painful, heals more quickly, and has fewer complications than the traditional vasectomy procedure. **(Read more about NSV and its U.S. introduction in *Contraceptive Technology Update*, March 1998, p. 29, and April 1999, p. 46.)**

Funded by The David and Lucile Packard Foundation of Los Altos, CA, AVSC is working in Colorado, Idaho, Tennessee, and Florida, says **Daria Teutonico**, AVSC program manager.

"We are working in anywhere from three to seven counties in each state, depending on the needs of the state health departments," says Teutonico. "AVSC provides training on vasectomy counseling, clinical training on the no-scalpel vasectomy procedure, and training on social marketing."

In addition, AVSC helps the health departments set up the vasectomy services and works with them in developing and implementing a social marketing campaign for the new procedure, says Teutonico.

Implementing the service

Johnson and fellow department provider Wendy Hearn, NP, underwent the provider training, while Julie White, RN, participated in sessions on NSV counseling and marketing issues. Johnson, who had performed traditional vasectomies prior to his administrative post, did a proctorship at the Golden clinic under one of AVSC's training physicians before offering the procedure.

An NSV procedure is broken into three office visits at the Golden department, says Johnson. The first visit includes the initial counseling required for informed consent, while the second includes the actual NSV procedure. A third visit entails testing of a sperm specimen to ensure the procedure has proven effective. NSV procedures are usually scheduled on Fridays to allow patients to recuperate over the weekend. AVSC patient literature recommends that men not do heavy physical labor for at least 48 hours after an NSV procedure. Many men have their vasectomies on Friday so they can take it easy over the weekend and go back to work on Monday, the literature states.

The county health department offers the procedure on a sliding scale fee basis, with the full price set at \$75. The state provided the department with \$100 funding for each of five clients in 1999, with

EXECUTIVE SUMMARY

The Jefferson County Department of Health and Environment in Golden, CO, is the first in its state to offer low-cost no-scalpel vasectomy (NSV) procedures.

- The department is one of several sites in an NSV project coordinated by AVSC International in New York City. AVSC is working in Colorado, Idaho, Tennessee, and Florida to train providers in the sterilization procedure.
- AVSC pioneered the introduction of NSV in the United States in 1988 following its 1985 visit to China to learn the technique developed by Li Shunqiang, MD. NSV is less invasive, less painful, heals more quickly, and has fewer complications than the traditional vasectomy procedure.

RESOURCE

- **AVSC International**, 79 Madison Ave., New York, NY 10016. Telephone: (212) 561-8000. Fax: (212) 779-9439. E-mail: info@avsc.org. Web: www.avsc.org. The Web site offers easy-to-read information on conventional and no-scalpel vasectomy methods and features a state-by-state listing of providers who offer no-scalpel vasectomies.

the same amount available through June 2000. The department hopes to continue such funding in the future, says Johnson.

At the Jefferson County facility, an active media relations campaign that draws on newspaper, radio, and television news has spread the word on the availability of the service, says Johnson. Posters in the department's five clinics have helped, as has information distributed by local Planned Parenthood organizations, he notes. "We have had good reception of the men who have come in. Almost all of them have said they were ready for this but couldn't afford it."

As with conventional vasectomy, no-scalpel vasectomy must be considered a permanent form of contraception, even though improved microsurgical techniques offer better chances of restoring fertility. The initial counseling session gives patients time to consider their decision, he notes.

Counseling helps eliminate myths about vasectomy. Many men incorrectly believe that vasectomy will cause impotence or cancer or result in weakened physical strength, weight gain, or development of a higher-pitched voice.³ Providers can explain that sterilization has no effect on masculine physical traits or normal sexual functions, and it can even improve sexual pleasure by reducing anxiety about accidental pregnancy.³ Still, be prepared if some patients may have a change of heart prior to the sterilization procedure.

"We have had probably four who have backed out or who are still waiting," Johnson notes. "We have had them scheduled twice, and they have said they are not quite ready."

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3. Keller S. Counseling encourages voluntary choice. *Network* 1997; 18:18-20. ■

'After the Fact, After the Act' spotlights EC

How do you get the message out about emergency contraception (EC) to women of color? In Philadelphia, coordinators hit the airwaves with strategically placed radio advertisements and followed up with brochures, fliers, and posters to promote their EC awareness message of "After the Fact, After the Act."

The program was sponsored by the Washington, DC-based Reproductive Health Technologies Project (RHTP), a nonprofit organization that helps provide public education and build understanding of safe, effective reproductive health technologies for women. The Project and the Office of Population Research at Princeton (NJ) University sponsor the Emergency Contraception Hotline, 888-NOT-2-LATE, and its companion Emergency Contraception Web site, <http://not-2-late.com>.

Hotline call volume following the radio ad campaign increased by 110%, compared with 10 weeks prior to the project, and it remained high for several weeks thereafter, says program assistant **Heather Zesiger**.

To examine the effectiveness of its existing EC material, RHTP conducted focus groups, says **Kirsten Moore**, RHTP project manager. Results led to the development of programs for hard-to-reach populations, including low-income urban African-Americans, she says. Funding from an independent health issues philanthropy, Kaiser Family Foundation of Menlo Park, CA, enabled RHTP to retain Motivational Educational Entertainment (MEE) Productions in Philadelphia to coordinate a similar educational campaign in that city.

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The 'After the Fact, After the Act' campaign in Philadelphia took the emergency contraception (EC) message to women of color through radio ads and distribution of brochures, fliers, and posters.

- Sponsored by the Reproductive Health Technologies Project, the campaign engaged more than 240 community organizations and opinion leaders to let women know about EC.
- Call volume for EC information following the radio ad campaign increased by 110%, compared with 10 weeks prior to the project, and it remained high for several weeks thereafter.

MEE specializes in socially responsible, research-based communications strategies targeting African-Americans, urban populations, and low-income youth on a wide range of topics, says Moore. It scheduled ads on top urban stations throughout much of July and August 1999 and supplemented them with features on local talk radio shows. The ads used a female narrator to inform audiences that “Sometimes we forget. Sometimes the condom breaks. Sometimes we’re raped. . . . Know that you have a second chance to prevent an unplanned pregnancy. With emergency contraception, it’s not too late to correct a mistake.” The ad gave further EC information and directed audiences to their health care providers or the hotline.

To reinforce the campaign message “on the ground,” MEE engaged more than 240 community-based organizations and opinion leaders as campaign partners, says Zesiger. The partners ranged from hair and nail salons to residents’ councils in public housing associations. All agreed to distribute brochures, fliers, and posters about emergency contraception and the hotline that were developed for the campaign.

The project and MEE also worked with more traditional partners in the health and family planning communities, including two local organizations, the Family Planning Council and CHOICE of Philadelphia, says Zesiger. Those organizations paid for an additional print run of 30,000 brochures with insert information on local clinics and the CHOICE hotline for distribution throughout their networks, she notes.

The Family Planning Council aided MEE in development of the Philadelphia EC brochure, which was widely distributed during Unity Day, a popular cultural arts event, as well as through the council’s extensive service network, according to **Kathie Nixon**, CRNP, RNC, the council’s director of patient services.

Believing access to EC goes hand in hand with awareness of the method, the council operates a service provider network to make EC available 24 hours a day, seven days a week. It tracks the network’s prescriptions of both emergent and prophylactic EC. Council figures do not reflect an increase in the number of women coming in for emergent EC during the awareness campaign; however, the campaign may have been too short in duration to impact usage, Nixon surmises.

Women at Genesis II/Caton Village, a Philadelphia drug and alcohol rehabilitation facility, didn’t know much about EC before the campaign started, says **Muriel Robinson**, a social work

counselor at the facility. Robinson used educational material, including the EC brochure distributed through MEE, in group sessions to explore women’s knowledge of EC, contraceptives, and sexually transmitted diseases. Posters about EC were displayed at the facility to keep awareness high.

In discussing contraceptives with the women, Robinson pointed out that methods can fail. When examining different types of condoms, she asked them, “Have you checked a condom for pinholes before it’s used? Do you know if the condom has been previously used?” Those types of questions led women to talk about the need for EC.

Each woman was given three EC brochures, says Robinson, one to keep and two to give sisters, daughters, other family members, and friends as women shared information on the method.

No woman has had to use EC since the awareness program was held, says Robinson. However, the campaign provided an entry into discussion surrounding sexual health that continues to this day, she notes. “Clients continue to keep journals on their attitudes about sex, sexual behaviors, safe sex, and other issues. That is something that I think is really great.” ■

Many teens not getting comprehensive sex ed

When adolescent patients enter your exam room, be prepared for them to possess limited, inaccurate, or no knowledge of contraception. According to a just-released study, one school district in three forbids dissemination of any positive information about contraception, regardless of whether students are sexually active or at risk of pregnancy or disease.¹

Among the seven in 10 public school districts that have a districtwide policy to teach sexuality education, 86% of them require that abstinence be promoted as the preferred or only option for teens. According to the nationally representative sample of 825 school districts, 51% have what is known as an abstinence-plus policy, which promotes abstinence as the preferred option for teens, yet allows contraception to be discussed as effective in protecting against unintended pregnancy, sexually transmitted diseases (STDs), and HIV.¹ A total of 35% of districts report they adhere to an abstinence-only policy, where teens are taught that abstinence is the only option outside of marriage.¹

EXECUTIVE SUMMARY

One U.S. school district in three forbids dissemination of any positive information about contraception, regardless of whether students are sexually active or at risk of pregnancy or disease, the latest research reveals.

- Among the seven in 10 public school districts that have a districtwide policy to teach sexuality education, 86% require that abstinence be promoted either as the preferred or only option for teens.
- The majority of Americans support sexual health information: More than eight of every 10 Americans believe young people should be given information to protect themselves from unplanned pregnancies and sexually transmitted diseases, as well as information about abstinence, according to national research.

“What this is saying is that at least one-third of students are receiving information about contraception that is extraordinarily limited, where either discussion of contraception is barred altogether or the emphasis is on its ineffectiveness in preventing pregnancy and guarding against sexually transmitted diseases,” observes **David Landry**, senior research associate at the Alan Guttmacher Institute in New York City and lead author of the study. “It is very important that providers fill in an essential gap that is not provided by many schools.”

A national survey of public secondary school

principals by the Kaiser Family Foundation of Menlo Park, CA, gives further insight in the limited education presented in public schools.²

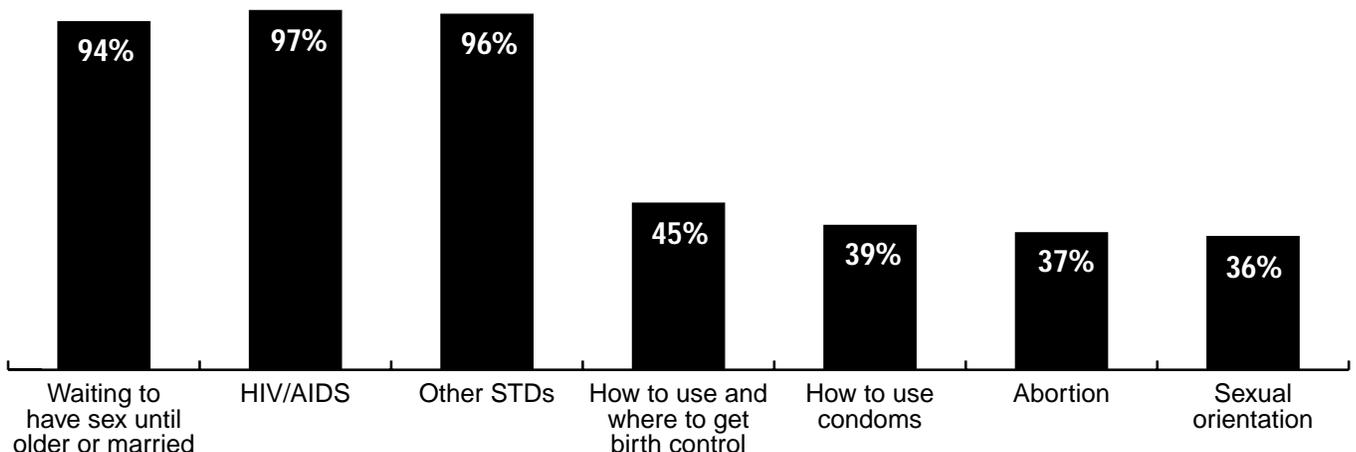
While 94% of public secondary schools discuss abstinence as part of their sex education and most cover HIV and other STDs, fewer than half say they provide information about where to get and how to use birth control and condoms. As many as one in two school programs do not discuss more controversial topics, such as abortion and sexual orientation, in their sex education curricula, the report reveals.

More than eight of every 10 Americans believe young people should receive information to protect themselves from pregnancies and STDs, as well as about abstinence, according to national research by the Washington, DC-based Advocates for Youth and the New York City-based Sexuality Information and Education Council of the United States (SIECUS).³ Ninety-three percent of all Americans support the teaching of sex education in high schools, while 84% support sex education in middle/junior high schools, the study reveals.

While debate continues to surround the teaching of sexual health, the SIECUS study shows that most Americans understand that both abstinence and comprehensive sexual health information can be presented, says **Monica Rodriguez**, SIECUS director of information and education.

“Parents understand that you can teach young people about abstinence, but you can also teach

Percentage of Principals Reporting Sex Education Topics Taught in Public Secondary Schools



Source: National Survey of Secondary Public School Principals, Kaiser Family Foundation. Conducted March 15 through May 3, 1999. Released at Emergency Issues in Reproductive Health Briefing, Dec. 14, 1999.

them about contraception and the things they need to know to protect themselves from STDs and HIV infection,” asserts Rodriguez. “In fact, they want their young people to have that information.”

Studies have shown that adolescents want more accurate information about sexuality, says Landry. “In many cases, unfortunately, students are not receiving it in the public schools, and they need a source that they can trust and that is reliable. Providers can help fill that void.”

At its December 1999 interim meeting, the Chicago-based American Medical Association’s House of Delegates accepted a report by its Council on Scientific Affairs that calls for comprehensive sex education. The report concluded that abstinence-only programs “are of very limited value and require additional, rigorous evaluation before they can be supported as a method for changing students’ risky practices.”⁴

Providers can get involved by obtaining copies of their local school district’s sex education curricula and checking them for accuracy, offers **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women’s health care clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance. “The medically incorrect statements included in typical abstinence-only programs are amazing, [so] offer to be the local expert,” she says. “It’s an effective way to influence the education the next generation receives.”

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3. Sexuality Information and Education Council of the United States. *Public Support for Sexuality Education Reaches Highest Level*. New York City; June 2, 1999.
4. Shelton DL. Does sex ed focused on abstinence work? *AM News* Jan. 17, 2000. ■

RESOURCE

- **SIECUS**, 130 W. 42nd St., Suite 350, New York, NY 10036-7802. Telephone: (212) 819-9770. Fax: (212) 819-9776. E-mail: siecus@siecus.org. Web: www.siecus.org.



Health education is focus of Web sites

Contraceptive *Technology Update* readers need information at their fingertips when providing patient education. Here are five good sites for some quick answers, with thanks to suggestions from **Sherry Carter**, MS, WHCNP, faculty associate and director of the women’s health nurse practitioner program at the University of Texas Southwestern Medical Center at Dallas, and **Lisa Koonin**, MN, MPH, chief of the surveillance unit, statistics, and computer resources branch in the Division of Reproductive Health in the Atlanta-based Centers for Disease Control and Prevention (CDC):

1. CDC’s Reproductive Health Site: www.cdc.gov/nccdphp/drh/. Because reproductive health issues are a focus of many CDC projects, this site features information from various programs, not just the Division of Reproductive Health and the National Center for Chronic Disease Prevention and Health Promotion. It carries information on unintended pregnancy, assisted reproductive technology, maternal health, men’s and women’s reproductive health, infant health, surveillance, research, and links to other sites.

2. HIV InSite: hivinsite.ucsf.edu. A comprehensive source of information on HIV/AIDS, HIV InSite is a project of the University of California at San Francisco’s (UCSF) Positive Health Program at San Francisco General Hospital Medical Center and the UCSF Center for AIDS Prevention Studies, programs of the UCSF AIDS Research Institute. Its medical information section carries patient fact sheets from a variety of sources; the site will post a cross-indexed guide to available patient fact sheets within the next few months. Other areas of interest include research, treatment guidelines, and current statistics on the epidemic.

3. National Women’s Health Information Center: www.4woman.gov. The National Women’s Health Information Center is a free service on women’s health issues designed to reach a broad audience, including consumers, health care professionals, researchers, and educators. A service of the

Washington, DC-based Office on Women's Health in the Department of Health and Human Services (HHS), the Web site provides a gateway to a wide array of federal and other women's health information resources. Site visitors can link to, read, and download material developed by HHS, other federal agencies, and private sector resources.

4. Healthtouch Online: www.healthtouch.com. A resource developed by Medical Strategies in Dublin, OH, Healthtouch Online offers information from national health organizations, including the CDC's Division of HIV/AIDS Prevention and the National Institute of Allergy and Infectious Diseases, on a comprehensive list of health conditions. The site carries a disclaimer that information may be downloaded and/or reprinted for personal use only.

5. Office of Disease Prevention and Health Promotion's The Year 2000 National Health Observances Web page. nhic-nt.health.org/Pubs/2000healthobserv/nho.htm. When is the Great American Smokeout? How about National Osteoporosis Prevention Month? This calendar from the Washington, DC-based Office of Disease Prevention and Health Promotion can help plan sponsorship of health promotion events, stimulate awareness of health risks, or focus on disease prevention. The site lists events by month, with names, contact information, e-mail addresses, and Web sites (if available), and denotes availability of educational materials.

The February 2000 *CTU* (p. 25) listed a number of Web sites that carry responsible reproductive health information for teens. Take a look at the following site, suggested by **Susan Wilson**, executive coordinator of the Network for Family Life Education, a component of Rutgers University School of Social Work in Piscataway, NJ:

6. The Network for Family Life Education Sex, Etc. newsletter: www.sxetc.org. The Network for Family Life Education established this sexuality and health newsletter "written by teens for teens" in 1994, with the help of two health educators and a professional journalist. Each year, the network recruits a new editorial board of high school students from New Jersey, New York, and Philadelphia. The editors develop story ideas and interview teens and adults for story information. A professional journalist helps teens turn interviews into stories; national correspondents from around the country also contribute stories. The Web site features an "Ask the Experts" section and offers information for adults to help them discuss sexual health issues with teens. ■



The politics of HPV: Legislation at issue

Conservatives using disease to further cause

By **Cynthia Dailard**
Senior Public Policy Associate
Alan Guttmacher Institute
Washington, DC

Conservative policy-makers on Capitol Hill have seized upon human papillomavirus (HPV) to advance their abstinence-only agenda. Genital HPV is an extremely common sexually transmitted disease (STD) that cannot be entirely prevented through condom use and is linked to cervical cancer. Based on this information, they believe HPV provides them with a silver bullet to discredit the notion of safe sex.

Conservatives also are using HPV to attack the family planning community — with its ongoing call for safer sex practices designed to reduce the risk for STDs and unintended pregnancy — for turning its back on this disease. However, the family planning community is teaming up with other public health advocates to educate policy-makers about the facts of HPV to achieve a more balanced public policy response to both HPV and cervical cancer.

*(Editor's note: To help answer questions surrounding HPV, a national hotline has been established as the first project of the new National HPV & Cervical Cancer Prevention Resource Center. The center has been launched by the Research Triangle Park, NC-based American Social Health Association, a nonprofit organization dedicated solely to the prevention and control of all STDs. Read more about the Center in the April 2000 issue of *Contraceptive Technology Update*, p. 46.)*

Congress first encountered HPV as a political issue in the context of the Breast and Cervical Cancer Prevention and Treatment Act of 1999 (HR 1070). That legislation is designed to help low-income, uninsured women with breast or cervical cancer obtain treatment. During

committee consideration of the bill, Rep. Tom Coburn (R-OK), a conservative physician and long-standing opponent of government-funded family planning programs, threatened to hold up consideration of the bill unless the committee accepted his amendments targeting HPV.

To ensure smooth passage of the bill, which is cosponsored by 280 members of the House of Representatives, the sponsors agreed to accept Coburn's amendments. Some of those proposals, however, are problematic from a public health perspective, not just from the standpoint of family planning advocates.

Condom warning labels proposed

One of Coburn's proposals requires the Atlanta-based Centers for Disease Control and Prevention (CDC) to enter into cooperative agreements with the states and other entities to conduct sentinel surveillance surveys to determine the prevalence of specific types of HPV. However, another proposal mandates that condom labels contain a cigarette-type warning stating that condoms do not protect against HPV and that HPV can cause cervical cancer.

In response to that provision, Rep. Henry Waxman (D-CA), a congressional leader on health care issues for more than 20 years, voiced the concerns of the public health community during committee consideration of the bill.

Waxman stated, "There is also a risk of unintentionally confusing the public about when condoms do or do not work. Condoms are unquestionably an important means of preventing the transmission of human immunodeficiency virus and other sexually transmitted diseases. But there is a danger that stressing a message about when condoms do not prevent the transmission of an STD may reduce their use in situations where they do, thereby increasing the transmission of STDs other than HPV.

"I also am concerned that mandating HPV information on condom labels, labeling, and advertising can result in so much information on such a small package that it ultimately reduces the effectiveness of any warnings or other information."¹

The proposed warning label would not make clear that there are many HPV types and not all lead to cervical cancer.² The label also would not help educate women that cervical cancer can be eliminated before it starts by receiving regular Pap tests to detect HPV infection and precancers.²

Groups such as the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) and the Chicago-based Society of Gynecologic Oncologists have expressed serious concern about the health message that might be received by the public if Coburn's proposal is enacted.² ACOG argued that HPV should not be singled out among all STDs and asked that information presented to consumers be based on accurate, medically based research.²

Public health advocates also take issue with Coburn's proposal to establish a process to lead to the required reporting of all cases of HPV to the CDC. Coburn suggests that such a measure would provide public health officials with vital information about the prevalence of HPV. His critics, however, contend that reporting all cases of HPV would not be worthwhile because many of those cases resolve on their own and only a small proportion leads to cervical cancer.

Bill in consideration

Having passed through the full committee, HR 1070 is awaiting consideration by the full House of Representatives. While the future of this bill is ultimately unclear, public health advocates hope to alter the more problematic HPV-related language as the bill moves through the legislative process. To cover his bases, however, Coburn has introduced his initiatives as a freestanding bill (HR 3248) as well.

Clearly, the politics of HPV have just begun, and HPV is likely to provide ample fodder for other debates surrounding publicly funded family planning programs, abstinence-only education, and other matters of public health.

(For additional information, see the article on HPV DNA testing research in *STD Quarterly* and the HPV consumer/patient fact sheet from the National HPV and Cervical Cancer Prevention Resource Center, both inserted in this issue.)

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Plan B ECP receives Canadian approval

Plan B, the levonorgestrel emergency contraceptive pill (ECP) from Women's Capital Corp. of Bellevue, WA, has received approval for Canadian distribution. The Canadian Therapeutic Products Programme's notice of compliance permitting the sale of the drug was announced by Paladin Labs of Montreal. Paladin holds exclusive Canadian distribution rights for the ECP. The company will launch Plan B in the second quarter of this year, according to **Jonathan Goodman**, Paladin president and CEO.

Preven, the ethinyl estradiol/levonorgestrel ECP from Gynetics of Belle Mead, NJ, is now on the Canadian market. It is distributed by Roberts Pharmaceutical Canada of Toronto. ▼

Self-learning modules target women's health

Women's health is the focus of two new CD-ROMs from the Washington, DC-based Association of Professors of Gynecology and Obstetrics (APGO). The self-learning programs are designed for use by multidisciplinary faculty, medical students, residents, and practitioners.

"Infectious Diseases in Obstetrics and Gynecology: A Tutorial" offers a detailed review of the principal infectious diseases encountered in OB/GYN. The review is presented through 37 interactive patient management scenarios, with users given a clinical scenario and asked questions related to pathogenesis, diagnosis, and treatment. Digitized images have been used to enhance clinical realism, with the narrative text providing explanation for correct and incorrect answers. A summary and set of learning objectives are presented at the end of each scenario.

"Women's Health Care Throughout the Life Cycle" covers a variety of women's health care topics that occur during the lifetime of several

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Association launches interactive quiz

Women and men can check their knowledge of current contraceptive methods through a new interactive quiz, "Test Your Contraceptive IQ," available on the Web site of the Washington, DC-based Association for Reproductive Health Professionals. The questionnaire can help those not currently using a contraceptive to consider their options, as well as allow those now using a method to see if it is being used correctly.

Click on "Test Your Contraceptive IQ" at the association's Web site, www.arhp.org, to check out the interactive quiz. ■

Correction

The correct definition for the acronym LSIL is Low-grade squamous intraepithelial lesion. A misspelling appeared in the article, "HPV hotline focus of new resource center," published in the April 2000 issue. ■

CE objectives

[For details on Contraceptive Technology Update's continuing education program, contact: Customer Service, American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub.com. Web: www.ahcpub.com.]

After reading *Contraceptive Technology Update*, the participant will be able to:

- Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. (See "Mifepristone approval delayed, supporters look to action by FDA," p. 53.)
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See "Expand male services: Add no-scalpel vasectomy," p. 56, and HPV DNA tests: Studies target use for cancer screening, *STD Quarterly*, p. 1.) ■

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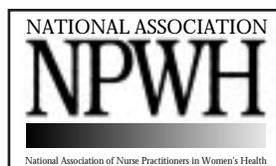
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S • T • D Q U A R T E R L Y™

HPV DNA tests: Studies target use for cancer screening

Evaluating new weapon in cervical cancer fight

Cervical cancer is a leading cause of cancer in women worldwide, with an estimated 400,000 cases diagnosed each year.¹ The cause of most of those cases? Researchers now point to human papillomavirus (HPV).²

While there are more than 30 genital types of HPV, only 10 to 15 types cause cancer.³ The prevalence of HPV in the United States is high: More than one-third of the estimated 15.3 million new cases of sexually transmitted diseases (STDs) in the United States in 1996 were attributed to HPV.⁴

While most HPV infections do not lead to serious problems, high-risk HPV types are responsible for nearly all cervical cancers. Now that scientists have firmly established the link between cervical cancer and HPV, they are turning their attention on how to use that information to decrease the morbidity and mortality associated with the disease.

The federal Food and Drug Administration gave approval in March 1999 to the Hybrid Capture II HPV Test, a DNA-based technology that can detect 13 high-risk types of HPV. The test is manufactured by Digene Corp. of Beltsville, MD. (*Contraceptive Technology Update reported on the Hybrid Capture II and its predecessor in April 1998, p. 48.*)

HPV DNA testing should become a routine way of screening women over the ages of 35-40 in the United States as soon as clinical trials can be conducted in this country, asserts **Thomas Wright Jr., MD**, associate professor in the department of pathology in the College of Physicians and Surgeons at Columbia University in New York

City. Wright served as lead author for a recently published study on HPV testing of self-collected vaginal swabs in a periurban population of South African women.⁵ Results from the cross-sectional observational study, which screened more than 1,400 women ages 35 to 65, indicate that HPV testing of such swabs is less specific than but as sensitive as Pap smears for detecting high-grade lesions in women ages 35 and older.

"[HPV DNA testing] is more sensitive than routine cytology, and I doubt much less specific in a low- or intermediate-risk U.S. older population," Wright observes. "In women, I would hope we would go to a combination of HPV and cytology and use a management algorithm in which

EXECUTIVE SUMMARY

Researchers are looking at DNA testing in the detection of high-risk types of human papillomavirus (HPV). While there are more than 30 genital types of HPV, 10 to 15 are responsible for almost all cervical cancer.

- The Hybrid Capture II HPV Test from Digene Corp. can detect 13 high-risk types of HPV.
- HPV DNA testing has limited potential to help direct decisions about clinical management of women with low-grade squamous intraepithelial lesion Pap smears, say scientists in a multisite study coordinated by the National Cancer Institute. Researchers are reviewing DNA testing in the management of women with atypical squamous cells of undetermined significance Pap smears.

the women negative on both tests get interval screening, whereas the women who are HPV DNA positive/Pap negative get repeat screens at six- to 12-month intervals until they become either HPV DNA negative or develop an abnormal smear.”

HPV testing can accurately identify most precancerous changes in the cervix and may be a useful screening tool in some populations, according to recent research that looked at DNA testing in women in a high-risk province of Costa Rica.⁶

“Our findings suggest that HPV testing is a viable technology worthy of consideration in cervical cancer prevention programs,” states **Mark Schiffman**, MD, an epidemiologist at the National Cancer Institute in Bethesda and the study’s principal investigator. However, study authors also caution that the usefulness of HPV testing will vary according to the population being screened and other factors, such as prevalence of other screening methods and cost.

“Decisions on optimal methods of screening will probably have to be made on a regional or national basis and depend on health economic analyses,” Schiffman says.

ASCUS, LSIL questions

Providers are familiar with the Pap smear, which is the most common tool in the fight against cervical cancer. It is estimated that early detection of pre-malignant lesions by Pap smears prevents at least 70% of potential cervical cancers.⁷ The incidence of invasive cervical cancer has decreased significantly over the last 40 years, in large part due to early detection efforts. The National Breast and Cervical Cancer Early Detection Program, operated by the Centers for Disease Control and Prevention in Atlanta, estimates 12,800 new cases in 1999, with 4,800 deaths attributed to the infection.

Providers are familiar with two of the classifications for reporting cervical and vaginal cytologic diagnoses: ASCUS (atypical squamous cells of undetermined significance) and LSIL (low-grade squamous intraepithelial lesions). Uncertainty about the management of such mild cervical lesions has caused provider headaches because most lesions regress and do not cause disease.⁸ Providers are puzzled about which lesions can be safely tracked with follow-up Pap tests and which may require immediate biopsy and follow-up.

Researchers hope that results from the ASCUS/LSIL Triage Study (ALTS) sponsored by the National Cancer Institute will yield the answers needed for developing clinical guidelines for managing mild lesions. A multisite investigation initiated in 1995, the study is looking at three ways to manage lesions:

1. watchful waiting with a follow-up Pap smear every six months;
2. immediate colposcopy and biopsy;
3. use of HPV DNA testing to identify women most likely to benefit from immediate colposcopy (HPV positive) and women most likely to be normal (HPV negative) who do not need colposcopy and can be reassured.⁸

Approximately 2% of the 50 million Pap smears performed each year in the United States are categorized as LSIL, with the average cost of management for such cases estimated at \$1,000 per woman.⁹ Because the majority of those lesions disappear spontaneously, identifying those that are most likely to progress would help to minimize patient anxiety and inconvenience, lower use of invasive testing, and save money.⁹

The latest report from the ALTS trial addresses the question of whether testing women who have LSIL diagnoses for HPV DNA is useful as a triage strategy.¹⁰ Women with a LSIL diagnosis were enrolled in clinical centers in Birmingham, Oklahoma City, Pittsburgh, and Seattle. Within six months of their diagnosis, women completed a standardized questionnaire and underwent a pelvic examination in which cervical specimens were collected for HPV DNA testing and Pap smears were repeated.

Cells taken from each woman were analyzed for HPV DNA using the Hybrid Capture II assay. In addition, cells from 210 of the women were tested for HPV DNA by polymerase chain reaction assays. The commercial technique detected HPV DNA in 82.9% of the specimens, while 81.4% of the specimens tested by both methods were positive by both methods.

Because a very high percentage of women with an LSIL diagnosis from Pap smears tested positive with the HPV DNA assay, there is limited potential for HPV DNA testing to help direct decisions about the clinical management of women with LSIL, researchers conclude.

The role of HPV testing in the management of women with ASCUS is still under study by the ALTS group.

The ALTS study also will offer a thorough understanding of the screening process and how it affects women, says **J. Thomas Cox, MD**, executive medical director of the National HPV & Cervical Cancer Prevention Resource Center. (The center, launched by the Research Triangle Park, NC-based American Social Health Association, offers information for providers and patients. See *CTU*, April 2000, p. 46.) Testing for HPV has been proposed as a less invasive way of resolving the persistent anxiety that often accompanies the prolonged uncertainty of cytologic follow-up and the more acute high anxiety generated among women referred for colposcopy.¹¹

"I think we will have a much better understanding of what is most anxiety-producing in women," Cox notes. "It is all anxiety-producing, but is it harder to go directly to colposcopy, or have an HPV test and find out that you have this STD, or to not really know what is going on for a couple of years in conservative management? I think we will have some terrific information when the study is completed."

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Take control during National HIV Testing Day

Take a look at your calendar. There is still time to plan for National HIV Testing Day, scheduled for June 27. The campaign for 2000 focuses on targeted outreach to the African-American and Latino communities; adolescents; young gay, bisexual, and transgendered men; and women of childbearing age, according to the Washington, DC-based National Association of People with AIDS (NAPWA).

NAPWA, along with several national partners, coordinates National HIV Testing Day, working with state and local organizations to develop events in their communities. The annual event's message, "Take the Test, Take Control," reinforces NAPWA's belief that participation in HIV antibody counseling and testing is a critical step in the decision to take responsibility for personal health.

The campaign was developed in 1995 to respond to the growing number of HIV infections among specific populations and the widespread ambivalence among many Americans about the value of knowing their HIV serostatus.

Testing has increased during campaign timeframes, from 1995 through 1998, with 1999 data still being evaluated, says **Anthony Farmer, MBA**,

EXECUTIVE SUMMARY

Get ready for National HIV Testing Day, scheduled for June 27. The Washington, DC-based National Association of People with AIDS and other national partners work with state and local organizations to develop events.

- The theme is "Take the Test, Take Control."
- The campaign was developed in 1995 to respond to the growing number of HIV infections among specific populations and the widespread ambivalence among many Americans about the value of knowing their HIV serostatus.

NAPWA's deputy executive director for operations and finance. The organization just completed a two-day National HIV Testing Advocacy Network conference in San Francisco, where participants shared successes from the 1999 campaign and planned for the upcoming event.

Two new items launched at the meeting include social marketing programs calling for NAPWA to collaborate with community-based organizations in developing campaigns targeting a specific population. By assisting with the planning, implementation, and evaluation, the campaigns can be developed as model programs for others to use in the future, says Farmer.

"The other thing we are launching is the National HIV Testing Advocacy Network," he says. "We are still in the planning stages with it, but with the campaign as a foundation, we want to formulate a network across the country to have a collective voice to stress the importance of HIV testing and knowing your serostatus and taking control of your health life."

Numbers up during week

The County of Los Angeles Department of Health Services' Office of AIDS Programs and Policy worked with its community-based organizations to reach a broad range of populations, particularly in African-American and Hispanic communities, including sexually active women, adolescents and young adults, and young gay, bisexual, and transgendered men. The multilevel campaign highlighted testing and counseling events held the week leading up to June 27, says **Sophia Rumanes**, MPH, program manager.

During the event week, 2,043 people were tested, compared with the average 1,387 weekly figure for 1999, says Rumanes. A total of 34 people tested positive during the week, compared with the average weekly figure of 24, she notes. Organizers also tracked the number of calls placed from Los Angeles County to the statewide AIDS hotline. "On an average week, it is estimated that LA County contributes to 36% of all the calls to the hotline, and during HIV Testing Days, 62% of all the calls to the hotline originated in LA County. The majority of the calls from LA County discussed testing issues."

Some 70 events were held during the week, with the county's community-based organizations heavily involved in the effort, says

Rumanes. Public relations and advertising efforts included local print and radio ads, billboards, bus bench placards, brochures, outreach cards, pamphlets, and fliers. Interviews with print, radio, and television stations also were coordinated through a press conference.

Community-based organizations also networked with businesses and other groups to obtain promotional items and incentives to encourage people to return to sites for their test results. Movie passes, compact discs, hygiene kits, food coupons, and restaurant certificates proved to be popular items, she notes.

To get your facility involved in National HIV Testing Day, consider joining in with other organizations in offering a health fair, suggests Farmers. Some people may not come specifically for HIV testing, but they'll participate if it's offered along with other kinds of tests. Neighborhood festivals also are a good site, he notes.

Companies such as Bristol-Myers Squibb Immunology in New York City and Epitope in Beaverton, OR, which have served as national sponsors, can provide assistance on the local level, Farmer says. Contact your sales representative if your facility plans to participate in the event, he says. A wealth of information developed during the 1999 campaign also is available on the Internet. **(See resource box, below. Also see patient handout, *Women and HIV/AIDS*, printed in English and Spanish, inserted in this issue.)**

If your facility will serve as a testing site during the event, plan to offer extended hours so people can take advantage of testing outside normal work hours, NAPWA suggests. Also, consider having volunteers to serve as testing buddies to answer questions about the counseling and testing process or to provide individual support during the waiting period for results. This is a very popular service for testing programs serving youth, NAPWA notes. ■

RESOURCE

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- Information from the 1999 campaign is available on the Web: www.hivtest.org.